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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,859	12/20/2001	J. Michael Ramstack	000166.0108-US01	1415

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EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,859	RAMSTACK ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-90,94-99 and 101-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-90,94-99 and 101-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/(8/28/02).* 7(3/31/04)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Receipt is acknowledged of the amendment, the remarks, the declaration, the IDS, the one month extension of time of 3/31/04. Applicant please note that an initialed copy of the Supplemental IDS filed on 8/28/02 has been provided. Claims 65,80 and 94 are currently amended. Claims 91-93,100 have been cancelled and new claims 116-118 have been added. Claims 65-90,94-99,101-118 are now pending.

Claims Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 65-90,94-99,101-115 and newly added claims 116-118 remain rejected under U.S.C. 103(a) as being unpatentable over Ramstack et al. (U.S. Patent No. 5,650,173).

Ramstack teaches a process for preparing biodegradable microspheres comprisinga polymer and an active. More specifically, the process entails blending at

The solvent blend containing the active and the polymer is then dispersed in an aqueous solution to form droplets. The resulting emulsion is then added to an aqueous extraction medium whereupon the biodegradable microparticles are formed (c 3, l 27-40). Ramstack et al. also teach that the polymer can be selected from polyglycolic acids and polylactic acids (c 7, l 28-35). Furthermore, Ramstack et al. teach that the solvent system which gives the most improved microparticle quality is ethyl acetate and benzyl alcohol (c 8, l 50-52). Lastly, Ramstack et al. teach that the active agent can be risperidone (c 26, claim 12).

Ramstack et al. do not specifically teach that the microparticles are "maintained" at "a certain temperature" for "a certain period of time". However, it is the position of the examiner that the cited reference still renders applicant's claimed process obvious. First, many of the claims do not specify a temperature. Second, even the claims which do specify a temperature, specify that it be between 20 to 25 degrees C. The examiner points out that this temperature range includes average room temperature. Therefore, all that is required to fulfill the limitations of applicant's instant claims is that after the formation of the microparticles, and prior to their use in a pharmaceutical composition, they are placed into any type of container in a normal room, and held there until they are needed for further pharmaceutical processing.

Additionally, it is within the ordinary skill of the pharmaceutical art to set aside a recently made batch of microparticles, allowing them to thoroughly dry, prior to using the microparticles in any further formulations. Additionally, it is within the knowledge of the ordinary artisan that increased dryiness equals increased flowability.

Also, absent evidence to the contrary, there has been no criticality placed on the length of time the microparticles are maintained at this temperature, or on the flowability index, or the angle of repose. It appears, from the teachings of both the cited reference and Applicant's teachings, that the two are achieving the same end result. Furthermore, regarding the flowability index and the angle of repose, the Office does not have the facilitities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same matieral structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips,* 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray,* 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the process disclosed by Ramstack to make microparticles, and then set aside these microparticles, prior to using them, to ensure thorough dryness. The expected result would be microparticles which are thoroughly dried prior to use, and therefore have increased flowability. Therefore, applicant's steps claiming maintaining the microparticles at a conditioning temperature for a period of time would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 65-86,88-90,94-99,101-111, 113-115 and newly added claims 116-118 remain rejected under 35 U.S.C. 103(a) as being unpatentable over "Use of polylactic acid for the preparation of microparticulate drug delivery systems" by Conti (hereafter Conti).

Conti discloses several processes for preparing microparticles. One of these processes is emulsion solvent extraction, which involves emulsifying, in an aqueous medium, a polymer previously dissolved in a volatile organic solvent. Conti further teaches that solid microspheres are recovered by filtration, washied and dried under vacuum (page 161). Additionally, Conti teaches that polylactic acid can be used as the polymer throughout.

Conti do not specifically teach that the microparticles are "maintained" at a "certain temperature" for a "certain period of time" However, it is the position of the examiner that the cited reference still renders applicant's claimed process obvious. First, many of the claims do not specify a temperature or a time frame. Second, even the claims which do specify a temperature, specify that it be between 20 to 25 degrees C. The examiner points out that this temperature range includes average room temperature. Therefore, all that is required to fulfill the limitations of applicant's instant claims is that after the formation of the microparticles, and prior to their use in a pharmaceutical composition, they are placed into any type of container in a normal room, and held there until they are needed for further pharmaceutical processing.

Additionally, it is within the ordinary skill of the pharmaceutical art to set aside a recently made batch of microparticles, allowing them to thoroughly dry, prior to using the

microparticles in any further formulations. Additionally, it is within the knowledge of the ordinary artisan that increased dryness equals increased flowability.

Also, absent evidence to the contrary, there has been no criticality placed on the length of time the microparticles are maintained at this temperature, or on the flowability index, or the angle of repose. It appears, from the teachings of both the cited reference and Applicant's teachings, that the two are achieving the same end result. Furthermore, regarding the flowability index and the angle of repose, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips,* 28 U.S.P.Q2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray,* 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Therefore, one of ordinary skill in the art would have been motivated to use the process disclosed by Conti to make microparticles, and then set aside these microparticles, prior to using them, to ensure thorough dryness. The expected result would be microparticles which are thoroughly dried prior to use, and therefore have increased flowability. Therefore, applicant's steps claiming maintaining the microparticles at a conditioning temperature for a period of time would have been obvious to one of ordinary skill in the art at the time the invention was made.

The declaration under 37 CFR 1.132 filed 3/31/04 is insufficient to overcome the rejection of claims 65-90,94-99,101-118 based upon the Ramstack et al. reference under 35 U.S.C. 103 as set forth in the last Office action because the declaration does not support a scientific data that presents a comparison of the claimed particles and the particles of the Ramstack reference.

Response to Arguments

Applicant's arguments filed 3/31/04 have been fully considered but they are not persuasive. Applicant argues that none of the documents discloses or suggests the measuring steps contained in the foregoing independent claims, or the more narrow claims depending therefrom. None of the documents discloses or suggests a maintaining step resulting in microparticles having such an angle of repose or flowability index as recited in independent claims 114 and 117, or the narrow claims depending therefrom.

In response to applicant's arguments, the selection of a flowability index is within the skill of the art, and therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard

Sharon Howard

March 16, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600